

Application No.: 09/678580

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REMARKS

Claims 33 and 66 have been amended to clarify the invention. In particular, the claims state that the single flexible flap "has only one free portion". This amendment raises no new issues and does not require any further searching by the Examiner. Accordingly, applicants ask that it be entered into the file.

Claims 33-58 and 60-67 have been rejected for double patenting over a number of copending applications. Applicants respectfully submit that this rejection cannot be sustained.

The present invention is directed to a filtering face mask that employs an exhalation valve to purge exhaled air from the mask interior. The exhalation valve includes a valve seat and a single flexible flap that has a stationary portion and one free portion. The free portion is disposed beneath the stationary portion when the filtering face mask is worn on a person. The flexible flap is also positioned on the valve seat such that it is pressed towards the seal surface in an abutting relationship with it when a fluid is not passing through the orifice. The valve cover is disposed over the valve seat and comprises a surface that mechanically holds the flexible flap against a flap-retaining surface on the valve seat.

Unlike the claims that are pending in the other copending applications cited by the Examiner, the present invention requires that the valve cover have a surface that mechanically holds the flexible flap against a flap-retaining surface. While the other copending applications may, more-or-less, claim an exhalation valve that has a flexible flap with a stationary portion and a free portion, they do not claim a valve cover that has a surface that mechanically holds the flexible flap against a flap retaining surface on the valve seat. Because this limitation is not recited in those applications, the double patenting rejection cannot be sustained.

Claims 33-36, 50-56, 58, 60, and 61-65 have been rejected over UK Patent Application GB 2,072,516A to Simpson in view of French Patent 1,209,475. Applicants respectfully submit that this rejection cannot be maintained for the reasons presented in applicants' Amendment mailed October 4, 2001. As previously indicated, the record does not identify any teaching or suggestion for combining the teachings of the French patent with those of Simpson. The Federal Circuit has held that broad conclusory statements regarding a combination of teachings do not provide evidence sufficient to sustain the combination.¹ Rather, the showing required to establish the

¹ *In re Dembiczak*, 50 USPQ 1614, 1617 (Fed. Cir. 1999) ("Broad conclusory statements regarding the teachings of multiple references, standing alone, are not 'evidence'.").

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combination "must be clear and particular".² The Examiner has taken the position "that one of ordinary skill would look to the art of valves (which includes French Patent ('475)) to address problems associated with protecting the valve element from debris and/or damage and for controlling the direction of fluid flow through the valve using a cover for such a valve." This position does not point to a clear and particular teaching of a suggestion to combine Simpson with the French patent. To the contrary, this is the kind of broad statement that the Federal Circuit has stated is not acceptable for establishing a combination of references. There are multitudes of references in the valve art. It simply cannot be the case that a person of ordinary skill would have looked at any and all references in the valve art in determining how to mount a flexible flap to a valve seat in an exhalation valve. The inventors' patent application should not be used as an instruction book on how to reconstruct the prior art.³ Under the Examiner's position, it would have been obvious to use any valve cover from any valve anywhere in the world, including high pressure valves that are used in fields wholly distinct from low pressure drop exhalation valves that are used on filtering face masks. The mere fact that it is possible to find two isolated disclosures that might be combined in such a way as to produce a new mechanical device does not necessarily render that device obvious unless the prior art contains something to suggest the desirability of the proposed combination.⁴

In addition, it does not appear that the French patent can be used in a Section 103 rejection because it is a nonanalogous publication. As the Examiner is aware, a reference can only be used in

² *Id.* ("The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular."); see also *Ruiz v. A.B. Chance Company*, 57 USPQ2d 1161, 1168 (Fed. Cir. 2000) ("...the showing of combinability must be 'clear and particular.'"); *Brown and Williamson Tobacco Corp. v. Phillip Morris Inc.*, 56 USPQ2d 1456, 1459 (Fed. Cir. 2000) ("However, the suggestion more often comes from the teachings of the pertinent references. This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not 'evidence.'"); and *Winner Int'l Royalty Corp. v. Ching-Rong Wang*, 53 USPQ 2d 1580, 1586-87 (Fed. Cir. 2000) ("Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be 'clear and particular.'").

³ See, *In re Dembiczak*, 50 USPQ2d at 1617 ("Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability—the essence of hindsight."); see also *Panduit Corp. v. Dennison Mfg. Co.*, 1 USPQ2d 1593 (Fed. Cir. 1987) (The court held that combination claims are not invalid based merely upon finding similar elements in separate prior art patents because such a holding would be contrary to the statute and would defeat the congressional purpose behind title 35.).

⁴ *Smithkline Diagnostics Inc. v. Helena Labs Corp.*, 8 USPQ2d 1468 (Fed. Cir. 1988) ("Merely pointing to a negative monitor in the prior art, which constitutes Helena's main argument to establish obviousness, is unpersuasive. Helena cannot pick and choose among the individual elements of assorted prior art references to recreate the claimed invention."); *C.R. Bard Inc. v. M3 Sys. Inc.*, 48 USPQ2d 1225 (Fed. Cir. 1998) ("There must be something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination (emphasis added)."); *In re Grahak*, 226 USPQ 870 (Fed. Cir. 1985).

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making an obviousness rejection if it either is (1) in the field of the applicants' endeavor or (2) reasonably pertinent to the particular problem with which the applicant was concerned.⁵ In order for a reference to be reasonably pertinent, the reference needs to be one that would have logically commended itself to the inventor's attention in considering the problem at hand.⁶

The French patent appears to reside in the field of a high-pressure valve for a conduit connection, which clearly is not in applicants' field of endeavor. Further, the French patent is not reasonably pertinent to the particular problem that confronted the applicants. In the present case, the applicants were concerned with providing an exhalation valve that would furnish the wearer with extraordinarily low pressure drops during an exhalation. This would allow the warm, moist exhaled air to be rapidly purged from the mask interior. The mounting of the flap to the valve seat also was important to the performance of the exhalation valve. There is nothing in the record, however, which shows that a publication pertaining to a high-pressure valve would have been reasonably pertinent to document solutions for providing a low pressure drop exhalation valve or for mounting the flap to the valve seat. Because the French patent does not reside in applicants' field of endeavor, and there is no evidence that it is reasonably pertinent to the problems that concerned the applicants, the reference cannot be used to sustain an obviousness rejection.


Accordingly, please favorably reconsider the obviousness rejection based on Simpson and the French patent.

Respectfully submitted,

Date

3/4/02

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⁵ *In re Oetiker*, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

⁶ *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992).

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

33. (amended) A filtering face mask that comprises:

- (a) a mask body that is adapted to fit over the nose and mouth of a wearer; and
- (b) an exhalation valve that is attached to the mask body, the exhalation valve

comprising:

- (1) a valve seat that comprises:

- (i) a seal surface;
- (ii) an orifice that is circumscribed by the seal surface; and
- (iii) a flap-retaining surface; and

(2) a single flexible flap that has a stationary portion and only one free portion and first and second opposing ends, the first end of the single flexible flap being associated with the stationary portion of the flap so as to remain at rest during an exhalation, and the second end being associated with the free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second end also being located below the first end when the filtering face mask is worn on a person, the flexible flap being positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice; and

(3) a valve cover that is disposed over the valve seat and that comprises a surface that mechanically holds the flexible flap against the flap-retaining surface.

66. (amended) A filtering face mask that comprises:

- (a) a mask body that is adapted to fit over the nose and mouth of a wearer; and
- (b) an exhalation valve that is attached to the mask body, the exhalation valve

comprising:

- (1) a valve seat that comprises:

- (i) a seal surface;
- (ii) an orifice that is surrounded by the seal surface; and
- (iii) a flap-retaining surface; and

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(2) a single flexible flap that has a stationary portion and [a] only one free portion and a peripheral edge that includes a stationary segment and a free segment, the stationary segment of the peripheral edge being associated with the stationary portion of the flap so as to remain at rest during an exhalation, and the free segment being associated with the one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the free segment also being located below the stationary segment when the filtering face mask is worn on a person and viewed from the front, the flexible flap being positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice; and

(3) a valve cover that is disposed over the valve seat and that comprises a surface that mechanically holds the flexible flap against the flap-retaining surface.